

ELECTRONIC SUBMISSION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/802,225 Confirmation No. 3564
Applicants : Florencia Lim et al.
Filed : March 16, 2004
Title : METHOD OF MAKING NONCOMPLIANT BALLOON
FOR A CATHETER
Art Unit : 1791
Examiner : Edmund H. Lee

Docket No.: : ACSC 68062 (G1339USD1)
Customer No. : 24201 July 30, 2010

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Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed April 2, 2010 in response to the Final Office Action mailed on November 5, 2009 and the Advisory Action mailed on March 10, 2010. A request for a two month extension of time along with the requisite fee is attached hereto.

INTRODUCTION

The present invention relates to a method of manufacturing a balloon for a balloon catheter such that the balloon is both radially as well as axially non-compliant. The present application, U.S. Serial No. 10/802,225 was filed on March 16, 2004 and claims benefit of filings extending back to December 8, 2000.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors FLORENCIA LIM, NIAN JIONG BEI and CHI LE LONG to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on December 5, 2000, November 28, 2000 and November 14, 2000 respectively, which was recorded by the U.S. Patent Office on December 8, 2000, beginning at Reel 011361, Frame 0363.

II. RELATED APPEALS AND INTERFERENCES

There are no other pending appeals, prior appeals, interferences, or judicial proceedings known to applicant or applicant's legal representative that directly affect or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

The present application was originally filed with claims 1-9. A preliminary amendment served to cancel claims 1-9 and add 10-13. Claims 14 and 15 were added by subsequent amendment.

Claims 10-15 are pending, have been finally rejected and are currently being appealed.

A clean copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

A response to the Final Office Action of November 9, 2009 in which no claims were amended was filed on February 5, 2010. In the Advisory Action of March 10, 2010 it was indicated that applicants' arguments were not found to be persuasive.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Sole independent claim 10 is supported in the specification as follows:

10. A method of making a radially and axially noncompliant balloon (page 27, lines 1-2) for a catheter, comprising
 - a) first extruding a tubular product formed at least in part of a block copolymer (page 27, lines 7-9; line 2), having a first outer diameter and a first inner diameter;
 - b) then, prior to any expansion, annealing the tubular product at not less than about 50°C (page 28, line 6).
 - c) then heating the tubular product at a first elevated temperature, and radially expanding the tubular product to a second outer diameter (page 22, lines 9 – 13);
 - d) then heating the expanded tubular product at a second elevated temperature not less than the first elevated temperature (page 22, line 22 – page 23, line 2); and

e) then cooling the expanded tubular product to form the noncompliant balloon (page 23, line 18).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action mailed November 5, 2009, the claims were rejected as follows:

GROUND I

Claim 10 was rejected under 35 U.S.C. §102(b) as anticipated by Wang et al. (USPN 5,348,538).

GROUND II

Claims 11-15 were rejected under 35 U.S.C. §103(a) as obvious over Wang et al. (USPN 5,348,538).

VII. ARGUMENT

GROUND I

Anticipation under 35 U.S.C. §102 requires "identity of invention." That is, the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1267, 20 USPQ2d 1746, 1748 (Fed.Cir. 1991); see also In re Spada , 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). Where the claim at issue is a method claim as is the case for Claim 10 here, "anticipation requires identity of the claimed process and a process of the

prior art; the claimed process, including **each step** thereof, must have been described or embodied, either expressly or inherently, in a single reference." Scripps Clinic & Research Foundation v. Genetech Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991).

In view of the foregoing, the five "steps" of Claim 10 must be found within the four corners of the '538 reference, either expressly or inherently, or the rejection is improper and must be withdrawn. Each of these steps will be taken in turn.

- a) *first extruding a tubular product formed at least in part of a block copolymer, having a first outer diameter and a first inner diameter;*

- b) *then, prior to any expansion, annealing the tubular product at not less than about 50°C;*

The Examiner does not specifically identify where in the '538 reference this step is taught. Rather, the Examiner contends that "the claimed process" is disclosed at "col 2, lns 41-50; col 9, lns 25-35; col 10, ln 65 – col 11, ln 15; and col 11, lns 47 – 60." [4/16/09 O.A., p. 2] The two steps therefore must be found in the cited passages. Turning to column 9 of the '538 reference, just before the Office Action's cited passage, we see the following:

"The process begins with a length of extruded tube However, the tube as it is received from the extrusion process can be pre stressed or stretched prior to subjecting it to the blow molding process." [Col 9 lines 17 – 25]

The patent then goes on to state, as cited in the Office Action:

"When it is desired to stretch the extruded tube, the starting tube is stretched to 1.5 – 3.0 times its initial length while submerged in water at a temperature of 90° C." [Col 9 lines 26 – 28]

The Office Action relies on this passage for a teaching of steps a and b of Claim 10. [Final Office Action, ¶5: "The stretching step of Wang et al does not preclude the tube from being annealed."] However, claim 10 clearly states that the tube is annealed "prior to any expansion." The Office Action's concession that annealing, if it indeed takes place during the tube's submersion, occurs "while" the tube is being stretched in the water bath, establishes quite unequivocally that the claimed step is not taught by the '538 reference.

In response to applicants' argument, an Advisory Action was entered by the Examiner on March 10, 2010. In the Advisory Action, the Examiner argued that "Wang also teaches a heating step prior to expansion of the tubular product, wherein the heating temperature and apparatus is the (sic) similar to the arrangement used to anneal the expanded tubular product (col 9, lns 21-32; col 11, lns 47-59). Nothing in either of these cited passages rehabilitates the previous inadequacies discussed above. Col 9, lines 21 – 32 **expressly** state that the tube is "stretched . . . while submerged in water." This is certainly not a teaching of "prior to any expansion, annealing the tubular product" as required by Claim 10. Col 11, lines 47 – 59 discuss annealing the tube after it has been subjected to the balloon molding process, so it too cannot establish the required teaching needed to anticipate claim 10. Certainly there has been no expressed teaching of the claimed

steps, at least nothing cited in the Final Office Action or the Advisory Action clearly establishes anticipation.

In the absence of any *expressed* teaching of the claimed step, it was incumbent on the Office Action to show the claimed step as inherently taught. But it is well established in patent law that inherency cannot be established by mere probability, or even a high likelihood. Rather, as the M.P.E.P. states, a rejection for an anticipation rejection would require in this case that the Office Action establish through evidence of record that Wang's disclosure **necessarily** teaches the tubular product was in fact annealed before any deformation. **M.P.E.P. §2131** ("when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill"). To satisfy a *prima facie* case of anticipation, therefore, it was incumbent upon the Examiner to demonstrate, through evidence of record, that Wang's disclosure **necessarily** performs the annealing step, and that Wang's tube was annealed before deformation, not that it *could* have been annealed or it *might* have been annealed, let alone that it *might* have been annealed while being stretched. Since no evidence of record was proffered to prove this contention, there has been no showing under either an expressed teaching or an inherent teaching, and the rejection does not satisfy the *prima facie* requirements for anticipation. Accordingly, it is properly withdrawn.

*c) then heating the tubular product at a first elevated temperature, and
radially expanding the tubular product to a second outer diameter;*

d) then heating the expanded tubular product at a second elevated temperature not less than the first elevated temperature;

The second issue is whether the claimed limitation of "not less than" was afforded its proper weight by the Examiner in view of the requirement for "identity of invention" needed for anticipation. The Final Office Action contended that the 95° C bath described at col 10 ln 65 to col 11 ln 15 satisfies step c. Therefore, in order to meet the limitation of step d, Wang must disclose somewhere that a second heating step is taught "not less than [95° C]." This is what the claim recites, and anticipation requires that this step be taught by Wang. But Wang instead teaches that the second elevated temperature may be greater or less than (and preferably much less than) the 95° C temperature of the first heating step. It must be kept in mind that this is a method claim, reciting steps, as opposed to an apparatus claims wherein any value in a range can anticipate a claimed range. Here, the step specifically precludes what Wang teaches, namely the use of a temperature below the temperature of the first heating step. Applicant respectfully submits that the words of the claimed step must be given their proper weight, and when the words are given their due weight and meaning there is no teaching in Wang of the claimed step. Accordingly, for this second and independent reason the rejection of Claim 10 is properly withdrawn.

Applicant has demonstrated that the rejection of Claim 10 fails to meet the criteria for a *prima facie* anticipation rejection under 35 U.S.C. §102 for two separate and independent reasons. In view of the foregoing, Applicant respectfully requests that the Board strike the rejection of Claim 10.

GROUND II

Claim 10 currently stands rejected by only a single rejection under 35 U.S.C. §102 based on USPN 5,348,538. If the anticipation rejection is found to be inadequate to satisfy the *prima facie* burden for anticipation for the reasons set forth above, no pending rejection of claim 10 remains. Claims 11-15 all depend from claim 10 and would therefore technically avoid any obvious rejections in view of all dependent claims necessarily being narrower than claim 10.

Nonetheless, it is respectfully submitted that claims 11-15 additionally avoid obviousness due to the non-obviousness of independent claim 10 in view of the same reference. As was set forth above, the Wang et al reference actually teaches away from any annealing of the tube **prior** to its longitudinal or even its radial expansion with the teaching at col 9, lines 32-34 wherein it is expressly stated that it is preferred that the balloon be molded "**soon** after the tube has been **extruded**", to insure that conditions of the tube, such as moisture content remain acceptable." In view of the fact that an annealing process is inherently time consuming (e.g. claim 11 – "16-24 hours"), "**soon after**" would connote the absence of an annealing step. Finally, the cited reference fails to teach a second heating step that is performed at a temperature of **not less** than the temperature at which the material is radially expanded. The reference describes a process wherein the expansion is performed at a temperature of 95C (col. 10, line 65 to col. 11, line 9) and a subsequent annealing at 25-100C, **preferably** 65-80C and thereby fails to teach that the annealing temperature **must** not be less than the expansion temperature.

As such, it is respectfully submitted that while the cited reference teaches a method of manufacturing a balloon, it does not teach or suggest the particular method that is currently being claimed and in fact teaches a markedly different process. Moreover, while the method taught in the reference provides for the

manufacture of a balloon having a non-linear compliance curve, the method of the present invention results in a non-compliant balloon using different materials (block copolymers) to do so. As such, it is respectfully submitted that a method that employs a different starting material, requires the performance of different sequence of steps to provide a balloon with different expansion characteristics cannot reasonably be considered to be obvious in view of the cited reference.

VIII. CLAIMS APPENDIX

An appendix containing a copy of the claims in this appeal are appended hereto as Exhibit 1.

IX. EVIDENCE APPENDIX

No evidence is submitted beyond this brief.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

As argued above, it is respectfully submitted that the present invention effectively avoids the cited art. Reversal of the rejections of claims 10-15 is therefore respectfully requested.

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/
Gunther O. Hanke
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LIST OF EXHIBITS

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
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1	Appealed Claims
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EXHIBIT 1

CLAIMS ON APPEAL:

10. A method of making a radially and axially noncompliant balloon for a catheter, comprising

- a) first extruding a tubular product formed at least in part of a block copolymer, having a first outer diameter and a first inner diameter;
- b) then, prior to any expansion, annealing the tubular product at not less than about 50°C.
- c) then heating the tubular product at a first elevated temperature, and radially expanding the tubular product to a second outer diameter;
- d) then heating the expanded tubular product at a second elevated temperature not less than the first elevated temperature; and
- e) then cooling the expanded tubular product to form the noncompliant balloon.

11. The method of claim 10 wherein the extruded tubular product is annealed for about 16 to about 24 hours.

12. The method of claim 10 wherein the extruded tubular product is annealed at about 55°C.

13. The method of claim 12 wherein the extruded tubular product is annealed for about 16 hours.

14. The method of claim 10 wherein the block copolymer is a polyurethane block copolymer, and the tubular product is radially expanded to a blow up ratio of greater than about 6 in c), wherein the blow up ratio is the ratio of

the second outer diameter of the expanded tubular product to the first inner diameter of the extruded tubular product.

15. The method of claim 14 wherein the polyurethane block copolymer is a polycarbonate polyurethane block copolymer comprising the product of the reaction of poly(1,6-hexyl 1,2-ethylcarbonate) diol and 4,4'-methylene bisphenyl diisocyanate (MDI) and a chain extender, and the noncompliant balloon has a rupture pressure of at least about 18 atmospheres, and the tubular product is radially expanded to a blow up ratio of about 7.4 to about 7.8 in c).